510 (K) Summary of Safety and Effectiveness for 'Medican Alpha'

DATE:	October 27, 2006
SUBMITTER:	EASTERN MEDIKIT LIMITED, 196, Udyog Vihar, Phase-1, Gurgaon-122 016 (Haryana)
CONTACT PERSON:	RAJEEV ASRI
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E-MAIL:	rajeevasri@medikit.com
TRADE NAME:	Medican Alpha
COMMON OR USUAL NAME:	CATHETER, INTRAVASCULAR, THERAPEUTIC, SHORT TERM (LESS THAN 30 DAYS). [Various Sizes of IV Catheters / Cannulae]
CLASSIFICATION NAME:	Catheter, intravascular, therapeutic, short term less than 30 days
DEVICE CLASSIFICATION:	Class II, 21 CFR 880.5200: Intravascular Catheter
PREDICATE DEVICE(S):	B. Braun Medical Inc. - 1-Introcan W [K 982805] Becton Dickinson - BD Insyte™ [K 013073]
DESCRIPTION:	As per ISO 10555-1, the generic definition of an intravascular catheter is - Intravascular catheter is a tubular device, single or multi lumen, designed to be partially or totally inserted into the cardiovascular system for diagnostic and/or therapeutic purpose The device under this submission is an over-needle-peripheral catheter. Over – the – needle peripheral intravascular catheters are intended for accessing the peripheral vascular system, supplied in the sterile condition and intended for single use. These catheters are designed for the introduction or withdrawal of liquids into or from the peripheral vascular system.
INTENDED USE:	Intravascular catheter is a medical device intended to be used to introduce fluids or medicament through the peripheral veins and / or withdrawal of blood samples. Intravascular catheter comprises of a short flexible plastic tube (the Catheter) which is inserted into a vein over a hollow introducer needle, after which the needle is withdrawn and discarded. The intravascular catheter is used in aseptic environment. Federal law (USA) restricts this device to sale by or on the order of a physician.
INDICATIONS FOR USE:	- Infusion of I.V. Solutions. - Intermittent intravenous Drug administration.

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SUMMARY OF NON-CLINICAL PERFORMANCES AND CONCLUSIONS:

In-vitro performance testing of the Medican Alpha included Design Qualification, visual analysis and Physical Analysis as per ISO 10555-1 & ISO 10555-5 [Sterile, Single-use intravascular catheter – (1) General requirements and (5) Over Needle Peripheral Catheter]. The Medican Alpha has also been tested for Physico-chemical testing like Non volatile residue, Heavy metals, Residue on ignition, Buffering capacity, Bacterial Endotoxin tests and Sterility test as per USP-29.

The results have confirmed that Medican Alpha meets the requirement for all general and specific requirements of ISO 10555-1 & ISO 10555-5; and also passes the Physiochemical, Bacterial Endotoxin and Sterility tests as per USP-29

The *Biocompatibility* of the Medican Alpha has been verified in accordance with ISO 10993-1:1997 (Biological Evaluation of Medical Devices). Test results confirmed Biocompatibility of the catheter when tested as an External Communicating, Circulating Blood contact, and prolonged Exposure (>24 hrs to 30 days) device.

SUBSTANTIAL EQUIVALENCE:

In comparative study of Medican Alpha IV Catheter with Becton Dickinson catheter premarket notification, BD Insyte, it is found that The Medican Alpha IV Catheter is similar in respect of material, design and intended use with Becton Dickinson catheter, "BD Insyte™". The only two major differences are [1)] presence of luer cap in Medikit Brand catheter and [2)] that of packaging (blister) material. A luer cap is an additional feature in Medican Alpha and does not alter any functional aspect of the device. The packaging material does not affect the functional use of product as both provide a sterile package till the shelf life period. Therefore, Medican Alpha may be considered as substantially equivalent to "BD Insyte™".

In comparative study of Medican Alpha IV Catheter with B Braun catheter premarket notification, 1-Introcan W, it is observed that The Medican Alpha IV Catheter is similar in respect of material, design and intended use with B Braun catheter, 1-Introcan W. The two major differences are [1)] the safety feature of the predicate device that is not present in the Medikit brand Medical Alpha and [2)] presence of luer cap in Medikit Brand catheter; this is an additional feature of Medican Alpha. Therefore, Medican Alpha may be considered as substantially equivalent to B Braun catheter, 1-Introcan W, except for the Safety features provided in B Braun 1-Introcan W.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Eastern Medikit Limited
C/O Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K063469
Trade/Device Name: Medican Alpha
Regulation Number: 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: II
Product Code: FOZ
Dated: November 15, 2006
Received: November 16, 2006

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

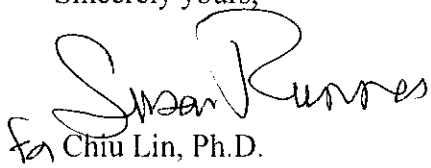
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): Not yet assigned

Device Name: Medican Alpha

Indications for Use:

- Infusion of I.V. Solutions.
- Intermittent intravenous Drug administration.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for AOW 12/1/06

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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